



**PATENT COOPERATION TREATY**

**PCT**

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 414/04400	<b>FOR FURTHER ACTION</b>		See Form PCT/PEA/416
International application No. PCT/IL2005/000135	International filing date (day/month/year) 04.02.2005	Priority date (day/month/year) 05.02.2004	
International Patent Classification (IPC) or national classification and IPC A61N1/00			
Applicant REABILITY INC. et al.			
<p>1. This report is the international preliminary examination report, established by this international Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 7 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau a total of 6 sheets, as follows:</p> <p style="margin-left: 20px;"><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 807 of the Administrative Instructions).</p> <p style="margin-left: 20px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand  05.12.2005	Date of completion of this report  23.01.2006		
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer  Kempin, H-F  Telephone No. +49 89 2399-2716  		

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International application No.  
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**Box No. 1 Basis of the report**

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
- international search (under Rules 12.3 and 23.1(b))
  - publication of the international application (under Rule 12.4)
  - international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

**Description, Pages**

1-20 as originally filed

**Claims, Numbers**

1-48 filed with telefax on 05.12.2005

**Drawings, Sheets**

1/5-5/5 as originally filed

- a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3.  The amendments have resulted in the cancellation of:
- the description, pages
  - the claims, Nos.
  - the drawings, sheets/figs
  - the sequence listing (*specify*):
  - any table(s) related to sequence listing (*specify*):
4.  This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- the description, pages
  - the claims, Nos.
  - the drawings, sheets/figs
  - the sequence listing (*specify*):
  - any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:
- the entire international application,
  - claims Nos. 36-46,48  
because:
    - the said international application, or the said claims Nos. 36-46,48 relate to the following subject matter which does not require an international preliminary examination (specify):  
**see separate sheet**
    - the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
    - the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
    - no international search report has been established for the said claims Nos. 36-46
    - the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
      - the written form  has not been furnished
      - does not comply with the standard
      - the computer readable form  has not been furnished
      - does not comply with the standard
    - the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
  - See separate sheet for further details

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting each statement**

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1. Statement

Novelty (N)	Yes: Claims	1-35,47
	No: Claims	
Inventive step (IS)	Yes: Claims	1-35,47
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-35,47
	No: Claims	

2. Citations and explanations (Rule 70.7):

**see separate sheet**

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**Box No. VIII Certain observations on the international application**

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The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

**Re Item III**

**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

Claims 36-46 and 48 relate to a method for treatment of the human or animal body by therapy. According to Rule 67.1(iv) PCT an International Preliminary Examining Authority is not required to carry out an examination for that kind of claim.

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Reference is made to the following documents:

D1: WO-A-02/092164

The document D1 is regarded as being the closest prior art to the subject-matter of claim 1 and shows (the references in parentheses applying to this document):

Apparatus for rehabilitating a patient who has a paretic body part, the apparatus comprising:

a) at least one electromyography EMG sensor adapted to being applied to a voluntary muscle of a healthy body part of the same type as the paretic body part, which at least one sensor produces at least one EMG signal (see the last paragraph on page 19);

b) a neuromuscular electrical stimulation NMES device adapted for stimulating at least one voluntary muscle of the paretic body part (see the paragraph bridging pages 17 and 18); and

c) a controller which controls the NMES device, said controller being configured to:

i) store a desired motion of said paretic body part (see 31 in figure 4 and page 20, paragraph 4).

The subject-matter of claim 1 differs from this known apparatus by features ii) and iii).

The subject-matter of claim 1 is therefore new (Article 33(2) PCT).

The problem to be solved by the present invention may be regarded as to improve the known apparatus so that it encourages the development of alternate pathways for nerve

impulses in the patient, or alternate locations in the motor cortex to originate nerve impulses to the muscles.

The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

There is no incitation in the available prior art to store in the controller NMES amplitude insufficient to cause said desired motion and to determine an amplitude of stimulation such that said NMES stimulation is not sufficient, on its own, to move said paretic body part with said desired motion.

Claims 2-30 and 47 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

Independent claim 31 includes in substance the essential distinguishing features of claim 1 (NMES amplitude insufficient to cause, on its own, desired motion but ...) and is considered new and inventive for the same reasons as claim 1. Dependent on claims 32-35 and 47 thus also meet the requirements of the PCT with respect to novelty and inventive step.

### **Re Item VIII**

#### **Certain observations on the international application**

1. Although claims 1 and 31 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.

2. The description is not in conformity with the claims as required by Rule 5.1(a)(iii) PCT.

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(SEPARATE SHEET)**

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3. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).